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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,789	04/15/2004	Douglas A. Hettrick	P0010880.00	6661

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EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	**PAPER NUMBER**
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/824,789	**Applicant(s)** HETTRICK ET AL.	
	Examiner Christopher A. Flory	**Art Unit** 3762	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 June 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): Claims 1, 12, 23 and 24 under 35 U.S.C. §112, first paragraph.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 1-24.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/George Manuel/
Primary Examiner
Art Unit 3762

Continuation of 11. does NOT place the application in condition for allowance because: Referring to claims 1-2, 12-13, 23 and 24, Mehra'459 teach a pacemaker that delivers tachyarrhythmia prevention therapy for an extended period of time (see Abstract). The pacemaker can employ a metric to determine if therapy is successful. The metric measured can be the frequency of occurrence of PACs, and further may be a defined range of PACs per hour, determined by the physician to represent an acceptable range of occurrences of PACs. The aggressiveness of the atrial arrhythmia prevention pacing modality employed may be increased in response to the number of occurrences of PACs being in excess of the defined endpoint range (see column 4, lines 5-12 and lines 30-38).

Further regarding claims 1, 12, 23 and 24, Mehra'459 is considered to disclose a means for detecting a sudden increase in the frequency of PACs insomuch as a change over a two-day period can be considered "sudden" in comparison to trends measured over weeks or months. Alternatively, even though the device of Mehra'459 is disclosed to monitor trends over certain periods of time with the examples of days, weeks or months, this does not preclude monitoring over shorter periods, also able to be considered of a sudden nature. Further, the Mehra'459 inherently must measure each heartbeat or PAC in order to trend such a statistic over a longer period of time, and therefore inherently detects changes on a beat-to-beat basis, which qualifies as a sudden increase.

Still further regarding claims 1, 12, 23 and 24, Mehra'459 inherently detects increases over a period of up to approximately one minute, since the Mehra'459 device can detect increases of periods longer than that, e.g. up to a period of days, weeks or months. Detecting increase over a two-day period inherently includes detecting increases over a time period of approximately one minute. Alternatively, it would have been obvious to one having ordinary skill in the art at the time of the invention to detect increases in first event frequency over a time period of one minute, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges (In re Aller, 105 USPQ 233) or optimum value of a result effective variable (In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)) involves only routine skill in the art. In this case, it would be obvious to measure increase over time periods of one minute when the intention is to update the delivered therapy on a more frequent basis.

Regarding claims 3 and 14, Mehra'459 teach that in response to an increase in PACs/day, the rate of the therapy may be increased (see column 21, lines 65-67 and column 22, lines 1-10). With reference to claims 4-5 and 15-16, Mehra'459 teach the device described above and further disclose that certain endpoints such as PACs/day and AF/day may be defined for a 24-hour period. Due to one or both of the PAC/day and AF/day values exceeding the defined acceptable ranges, the pacing parameters are adjusted to be more aggressive by either increasing or decreasing the rate. During a new 24-hour period, data is collected with the newly adjusted endpoints (see column 21, lines 57-67 and column 22, lines 1-15). With regards to claims 6-7 and 17-18, Mehra'459 disclose that the metric used to optimize the parameters of the arrhythmia prevention pacing modality may also be employed to disable the arrhythmia prevention pacing modality or to trigger the switch to an alternative pacing prevention modality (see column 4, lines 45-51). While not stated explicitly, it is inherent that arrhythmia detection subsequent to therapy is employed since the therapy is arrhythmia prevention pacing modality, and detecting an arrhythmia would prove the pacing to be ineffective.

Mehra'459 disclose the claimed invention except for determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system and method for controlling therapy in an implantable medical device as taught by Mehra et al, with determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold since it was known in the art that determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold is used to provide accurate and effective therapy and to prevent further damage to the patient.

Additionally, Mehra'459 discloses the claimed invention but do not disclose expressly the determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the system and method for controlling therapy in an implantable medical device as taught by Mehra'459 with the determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold, because Applicant has not disclosed that determining whether the second event is detected during delivery of therapy; determining whether therapy has been delivered a predetermined number of times; or determining whether the therapy has been delivered more than a predetermined time threshold provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with determining whether the second event is detected subsequent to delivery of therapy and determining whether therapy has been delivered for a predetermined time threshold (see figure 11), because it is used to provide accurate and effective therapy and to prevent further damage to the patient and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Mehra'459 Therefore, it would have been an obvious matter of design choice to modify Mehra'459 to obtain the invention as specified in the claims..